K041389

OCT 1 - 2004

3.0 Premarket Notification 510 (k) Summary

Date Prepared:	May 21, 2004
Sponsor Information:	
Name and Address:	SYNTHES® Spine. 1230 Wilson Drive West Chester, PA 19380
Telephone:	(484) 356-9616
Contact Person:	Angela Mikroulis
Device Name:	
Trade or Proprietary Name:	SYNTHES® Contoured SynMesh® Spacer
Common Name:	Implant, fixation, spinal intervertebral body fixation orthosis device.
Classification Name/Class:	Per 21 CFR 888.3060: Spinal intervertebral body fixation orthosis, Class II.
Device Description:	The SYNTHES® Contoured SynMesh® Spacer is a titanium vertebral body replacement device used in conjunction with supplemental internal fixation to provide structural stability in skeletally mature individuals following corpectomy / vertebrectomy.
Predicate Device (s):	SYNTHES® SynMesh® Spacer System (K003275)
Intended Use:	The SYNTHES® Contoured SynMesh® Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The SYNTHES® Contoured SynMesh® Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.
Material:	Commercially pure titanium
Substantial Equivalence:	Documentation is provided which demonstrates that the SYNTHES® Contoured SynMesh® Spacer for Spinal intervertebral body fixation orthosis is Substantially Equivalent to other legally marketed SYNTHES® devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

Ms. Angela Mikroulis
Regulatory Affairs Specialist
Synthes Spine
1230 Wilson Drive
West Chester, Pennsylvania 19380

Re: K041389
Trade/Device Name: SYNTHES® Contoured SynMesh® Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: September 1, 2004
Received: September 3, 2004

Dear Ms. Mikroulis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D.,M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K041389

Device Name: SYNTHES® Contoured SynMesh® Spacer

Indications for Use: SYNTHES® Contoured SynMesh® Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The SYNTHES® Contoured SynMesh® Spacer is intended to be used with SYNTHES® supplemental internal fixation systems, e.g., ATLP, Ventrofix, TSLP, and USS, Dual Opening USS, Small Stature USS, and Click'X. The interior of the spacer component of the SYNTHES® SynMesh® Spacer can be packed with bone.

SYNTHES® Contoured SynMesh® Spacer is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

for Mark N. Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041389

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